K040366 MAR - 4 2004

Fisher&Paykel HEALTHCARE

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12 Feb 2004

510(k) Summary of Safety and Effectiveness Information

Model/Name:	BC110 Pressure Manifold
Classification Name:	Non-rebreathing valve-73 CBP Anesthesiology, 21 CFR §868.5870 (Class II)
Predicate Device:	AirLife Inc. Whistler In-line Pressure Release Valve K831246
Classification Name:	Non-rebreathing valve-73 CBP Anesthesiology, 21 CFR §868.5870 (Class II)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

(a)(1) - (a)(3) (refer to information above and concluding this summary)

(a)(4) Description of the Device

The BC110 Pressure Manifold is an inline pressure relief device designed to protect pediatric/infant patients from excessive pressure in the event of a downstream occlusion occurring in positive pressure breathing systems. The BC110 pressure manifold also provides ports to allow the connection of external pressure monitoring devices and air/oxygen analyzers. The device consists of a rigid plastic tube, open at both ends, containing side ports and a side mounted pressure relief valve. The valve reacts instantaneously to an occlusion and automatically resets upon release of the occlusion. The inlet port for the gas source consists of a barbed connector, the outlet port for the patient connection is a 22/15 mm female.

(a)(5) Statement of the Intended Use

The BC110 Pressure Manifold is designed to protect pediatric/infant patients from excessive inspiratory pressure in the event of a downstream occlusion occurring in positive pressure breathing systems. The device is intended for use with flow rates greater than 0 L/min up to, and including, 15 L/min. The BC110 is fitted upstream of the patient. The BC110 is for single patient use and is prescription only.

(a)(6) Technological Characteristics Summary

The body of the BC110 is molded ABS plastic, the port caps are polyethylene. The overall length of the device is 134 mm, the overall diameter 25 mm and depth/height 58 mm. The inlet connector consists of a standard barbed O_2 connector made from polystyrene and is supplied pre-fitted to the manifold. The outlet connector is part of the manifold body and is a dual connector consisting of a 22 mm female or 15 mm female port. The O_2 analyzer port is also part of the manifold body and is a dual connector consisting of 22 mm male or 15 mm female port. The pressure ports, also part of the manifold body, consist of a female Luer and a 4 or 6 mm male push on. A flow direction arrow is molded into the side of the manifold body to indicate the correct setup position (this is supplemented by different connector sizes at each end). The ISO symbol for 'Single Use Only' is also molded into the side of the manifold. The pressure relief valve utilizes a stainless steel coil spring. An "anti-tampering" shroud covers the valve to ensure the factory set relief pressure (17 cm H2O at 8 Lpm) is not changed. Pressure relief at the maximum recommended flow rate of 15 Lpm is 24 cm H_2O.

(b)(1) Discussion of the Non-Clinical Tests

The following tests have been performed: Change in relief pressure with flow rate, leak testing, response time to an occlusion, performance on wet side of humidification chamber, accelerated life testing, calibration testing of test equipment.
Each pressure manifold is individually tested at the factory to ensure correct operation of the pressure relief valve.

(b)(2) Discussion of the Clinical Tests

None submitted.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The value of the set pressure of the relief valve is based on clinical evidence and is well within the limits for neonates stated in all relevant ventilator and resuscitation standards. Additionally, the pressure relief value is set and tested at manufacture and cannot be accidently or deliberately adjusted by the user.

The design of the valve and manifold minimises the chances of user error. User instructions specify the conditions of use. The device is labeled clearly as single patient use and disposable.

The operational performance of the pressure manifold has been tested under the likely conditions of use. Additionally, accelerated life testing has been performed over and above the time likely required for single use.

The Pressure Manifold is safe and effective for its intended use.

signed: Robert Petry date: 12 Feb 2004

Robert Petry
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2004

Mr. Robert Petry
Regulatory Affairs Engineer
Fisher & Paykel Healthcare Limited
P.O. Box 14-348
Panmure, Auckland
New Zealand

Re: K040366
Trade/Device Name: BC110 Pressure Manifold
Regulation Number: 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: February 12, 2004
Received: February 13, 2004

Dear Mr. Petry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040366

Device Name: BC110 Pressure Manifold

Indications for Use:

The BC110 Pressure Manifold is intended for use with 'positive pressure' breathing gas delivery systems for pediatric patients. The device is placed upstream of the patient in-line with the circuit and contains a pressure relief valve to protect the patient from excessive inspiratory pressure in the event of a downstream occlusion. The device also provides ports to allow the connection of external pressure monitoring devices and air/oxygen analyzers.

The device is intended for use with flow rates of 0-15 L/min. The relief pressure at 8 L/min is 17 cm H_2O. The relief pressure at 15 L/min is 24 cm H_2O.

The BC110 is disposable, single patient use and is prescription only.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040366